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MV

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/189,028	11/10/98	RASMUSSEN	3469.224-US

EXAMINER: G

HM12/0831

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ART UNIT	PAPER NUMBER
1652	5

DATE MAILED: 08/31/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/10/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 32-49 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 32-49 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. Substitute
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☒ received in Application No. (Series Code/Serial Number) 08/389,423.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
☐ Interview Summary, PTO-413

Substitute

DETAILED ACTION

1. This application has been filed with informal drawings which are acceptable for examination purposes only, please refer to the attached substitute PTO-948 form for details. Formal drawings will be required when the application is allowed.

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. § 119. The certified copy has been filed in parent Application No. 08/389,423, filed on February 14, 1995.

3. Claims 32-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ a novel antibody, AS 169. Since the antibody is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the antibody is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the antibody. The specification does not disclose a repeatable process to obtain the claimed antibody and it is not apparent if the claimed antibody is readily available to the public.

Although the application is sufficiently enabling to permit one of skill to immunize rabbits with the endoglucanase of the instant invention, as recited on pp. 14-15, the antibodies thus obtained would not *a priori* be exactly the same as AS 169. Thus, a deposit is required for enablement purposes.

If the deposit has been made under the terms of the Budapest Treaty, then the specification should be amended to recite, as required under 37 C.F.R. 1.801-1.809 (see MPEP § 2402-2411.05):

a. the accession number of the deposit;

b. the date of deposit;

c. a description of the deposited biological material sufficient to specifically identify it and to permit examination; and,

d. the name and address of the depository.

Also, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, is required stating that the specific antibody has been deposited under the Budapest Treaty and that the antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

e. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

f. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

g. the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

h. the deposit will be replaced if it should ever become inviable.

4. Claims 32-49 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to enzymes with Seq ID Nos.: 2 and 4. Although the specification teaches the production of cellulase preparations consisting essentially of an endoglucanase from

Humicola insolens DSM 1800 or an endoglucanase from *Fusarium oxysporum* DSM 2672, it lacks guidance for any cellulase preparation from the same, or any other, organisms which is active between pH 6.0 and 10.0 and is "immunoreactive" with an uncharacterized antibody, AS 169. The specification does not present sufficient guidance about the presence of other endoglucanases, in the same or other organisms, which meet these requirements and are useful in detergent compositions.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands, 858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The predictability as to the level of conservation between the disclosed sequences and those of other enzymes, if they exist, is extremely complex since a DNA sequence determines the structural and functional properties of a protein and knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation. Since detailed information regarding the structural and functional requirements of the endoglucanase polypeptides is lacking, it is unpredictable as to whether the disclosed sequences can be used to isolate other endoglucanases or other endoglucanase encoding DNA molecules. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of DNA molecules where the expectation of obtaining similar activity is unpredictable based on the instant disclosure.

As discussed, much is known about protein purification, however, it is not routine in the art to screen large amounts of cell cytoplasm preparations, protein preparations or culture media using an undefined antibody, with the expectation of discovering an enzyme, but without

any guidance or working examples as to the presence or absence of enzymes or any other proteins, which are "immunoreactive" with the antibody. It is also not routine to attempt to use an enzyme when no information is presented about the requirements of that enzyme for media, stability, temperature, co-factors, pH, etc. Therefore, one of ordinary skill would require guidance, in order to make and use endoglucanases, other than those of Seq. ID Nos.: 2 and 4, in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

5. Claims 41 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claims with the phrase "a higher degree of specificity". This could apply to the specificity of substrate recognition, the specificity of cutting sites or the specificity of activity.

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 32-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims issuing in U.S. Patent No. 5,948,642, the parent case of the instant application. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the patented claims recite "[a]n isolated enzyme exhibiting endoglucanase activity" which comprises Seq. ID No.: 2 or which is encoded by a polynucleotide amplified using a specific set of primers isolated from the instant organisms, along with claims to the enzyme as a detergent additive, a detergent composition comprising the enzyme, and part of various methods using the enzyme, and are encompassed by the instantly-claimed subject matter, which is directed to endoglucanase enzymes, endoglucanase as a detergent additive, and various methods of using endoglucanase.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbesgaard et al. [US Pat. 4,435,307], Ortega [(1991) Chemical Abstracts 114(15): 619, number 141530g] and Janson [(1984) Trends in Biotechnol 2(2): 31-38]. Barbesgaard et al. teach cellulase preparations, and detergent compositions comprising the cellulase preparations, isolated from *Humicola insolens* DSM 1800 which preparations are active at alkaline pH values (col. 3, lines 15-20) and at about 50°C (col. 12, lines 25-30). They teach the use of the compositions as harshness reducing agents (Examples 2-5). They teach the preparations in combination with surfactants (col. 5, lines 58-64) and other proteolytic enzymes (col. 6, lines 8-9). Ortega teaches a cellulase, expressed constitutively, isolated from *Fusarium oxysporum*. Janson teaches techniques of large scale protein purification, including affinity chromatography using antibodies (Table 1).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the teachings of Barbesgaard et al. and Ortega, that cellulase enzymes are

produced by *H.insolens* and *F.oxysporum*, with the teachings of Janson, that enzymes may be purified on a large scale, to obtain cellulase preparations which consist essentially of a homogenous enzyme component. Barbesgaard et al. further teach the use of enzymes in as harshness reducing agents in detergent preparations alone, or in combination with surfactants, various chemicals and other proteolytic enzymes. One would be motivated to do this in order to obtain useful detergent compositions, comprising purified cellulase having a highly active enzyme component, that can be produced in higher yields (Barbesgaard et al. col. 1, lines 46-48) and is active at higher pH and lower temperatures, which normally prevail in main wash solutions (Barbesgaard et al. col. 2, lines 20-24 and col. 7, lines 19-22). One would have a reasonable expectation of success since Barbesgaard et al. and Ortega teach that the enzymes are present, Janson teaches methods of purification and Barbesgaard et al. teach detergent compositions comprising cellulase enzymes.

The enzymes of the instant invention do appear to be different from the preparation of Barbesgaard et al., as shown in Examples 4 and 6, however the current rejection is not applied to Seq. ID Nos.: 2 and 4 or to enzymes isolated with the specific PCR primers recited, the enzymes allowed in the parent case, but against the general claims that could apply to various enzymes which could be isolated from the same organisms, or from any organism, and be reactive with an uncharacterized antibody.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

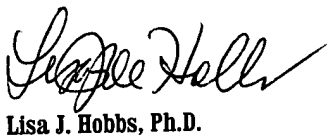
9. Any inquiry concerning this communication or earlier communications should be directed to Lisa J. Hobbs whose telephone number is (703) 308-6573. The examiner can

normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also be reached on alternate Fridays from 6:30 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission to the attention of the examiner in Art Unit 1652. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The FAX telephone number is (703) 308-4242. Note: If applicants do submit a paper by facsimile, the original signed copy should be retained by applicants or applicants' representative. No duplicate copies should be submitted so as to avoid the processing of duplicate papers in the Office.



Lisa J. Hobbs, Ph.D.
Primary Examiner
Art Unit 1652

August 28, 1999